

REMARKS

The outstanding Office Action requires that Applicants elect one of the following eight (8) allegedly distinct inventions:

- I. Claims 1, 83-95, 99 and 104, drawn to a method of treatment using NKT cells to promote inflammation, classified in Class 424, subclass 93.1.
- II. Claims 3, 5-15, 19, 24 and 32, drawn to a method of treatment using NKT cells as an anti-inflammatory, classified in Class 424, subclass 93.21.
- III. Claims 16-18, 20, 23, 96-98, 100 and 103, drawn to a method of treatment using oral tolerization to elicit up or down regulation of the immune system, classified in Class 424, subclass 184.1.
- IV. Claims 21 and 22, drawn to a method of treatment using NKT cells as an anti-inflammatory further comprising using oral tolerization to elicit up or down regulation of the immune system, classified in Class 424, subclass 185.1.
- V. Claims 33-39, 41-46 and 50-63, drawn to ex-vivo educated NKT cells capable of acting as anti-inflammatory agents, classified in 424, subclass 93.7.
- VI. Claims 66-72, drawn to antibody that recognizes NKT cells, classified in Class 424, subclass 130.1.
- VII. Claims 101 and 102, drawn to a method of treatment using NKT cells to promote inflammation further comprising using oral tolerization to elicit up or down regulation of the immune system, classified in Class 424, subclass 184.1.
- VIII. Claims 113-126, 130 and 131, drawn to ex-vivo educated NKT cells capable of acting as pro-inflammatory agents, classified in Class 424, subclass 93.71.

Applicants respectfully request reconsideration of the Restriction Requirement in view of the following remarks concerning the elections made herein.

First, restriction between inventions is only proper when a search burden exists for the Examiner to search all of the inventions claimed. If the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits,

even though it includes claims to independent or distinct inventions (see MPEP § 803.01). In the instant case, all eight Groups are drawn to methods or compositions for treating disease and all eight groups are classified in Class 424. Further, Groups I, II, IV, V, VII, and VIII all manipulate the NKT cell population in some way to modulate the Th1/Th2 cell balance. Moreover, Groups I, II, IV, V, VII, and VIII all show that the NKT cells are manipulated by “educating” them. As such, since these six groups are related and overlap, they should not be categorized as different inventions since a search of their subject matter would not constitute a serious search burden for the Examiner.

Secondly, the Office Action did not elucidate reasons and examples as required by MPEP 803 to support restriction between the various immune-related or immune-mediated disorders as distinct and independent. It is improper to restrict between these diseases because that are all diseases relating to the immune system that result from a shift in the Th1/Th2 balance towards a pro-inflammatory response.

Thirdly, the Office Action did not elucidate reasons and examples as required by MPEP 803 to support restriction between the sets of culture conditions for the ex-vivo education of NKT cells as distinct and independent. It is also unclear from the Office Action whether this was a restriction between the three sets of culture conditions (antigens or epitopes, liver-associated cells or cytokine/adhesion molecules) or a restriction within each set of culture conditions (thereby having to choose from the list of antigens if “antigens or epitopes” are chosen, for example). It is improper to restrict between the sets of culture conditions because all three of them are necessary to educate the NKT cells. All three sets are needed for the invention to be successful.

In view of the above remarks, it is respectfully requested that the Restriction Requirement be withdrawn and that all claims be allowed to be prosecuted in the same patent application. In the event that the requirement is made final and in order to comply with 37 C.F.R. §1.143, Applicants reaffirm the election with traverse of claims 3, 5-15, 19, 24 and 32 (Group II), holding the rest of the claims in abeyance under the provisions of 37 C.F.R. §1.142(b) until final disposition of the elected claims.

CONCLUSION

Applicants maintain that the restriction requirements is improper and that all pending claims should be examined for patentability. If the examiner believes that the prosecution might be advanced by discussing the application with Applicant's attorney, he should kindly contact the undersigned.

No fee is believed due in connection with this Amendment. If any fee or fees are due, however, the Patent and Trademark Office is hereby authorized to charge the amount of any such fee to Deposit Account 05-1135, or to credit any overpayment thereto.

Early and favorable action is respectfully requested.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Natalie Bogdanos". The signature is fluid and cursive, with the first name "Natalie" written in a larger, more prominent script than the last name "Bogdanos".

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